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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,142	10/30/2003	Charles P. Semba	P1989R1	9767

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EXAMINER	
UNDERDAHL, THANE E	
ART UNIT	**PAPER NUMBER**
1651	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/697,142	SEMBA, CHARLES P.	
	Examiner	Art Unit	
	Thane Underdahl	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-35* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7 are drawn to a solution comprising about 0.01 to 0.05 mg/mL of tenecteplase in sterile water for injection or bacteriostatic water for injection and normal saline., classified in class 424, subclass 183.

II. Claims 8-19 are drawn to a method for treating a pathological collection of a fibrin-rich fluid comprising exposing the fluid to an effective amount of a solution comprising about 0.01 to 0.05 mg/mL of tenecteplase in sterile water for injection or bacteriostatic water for injection and normal saline, classified in class 424, subclass 212.

III. Claims 20-26 are drawn to a method for treating peripheral thrombosis in a mammal comprising delivering to the mammal via a catheter an effective amount of a solution comprising about 0.01 to 0.05 mg/mL of tenecteplase in sterile water for injection or bacteriostatic water for injection and normal saline., classified in class 424, subclass 214.

IV. Claims 27-32 are drawn to A kit comprising a container comprising lyophilized tenecteplase, a container comprising sterile water for injection or bacteriostatic water for injection, a container comprising normal saline, and instructions for reconstituting the tenecteplase with the water for injection and diluting the reconstituted tenecteplase with the normal saline to a final concentration of about 0.01 to 0.05 mg/mL of tenecteplase., classified in class 424, subclass 212.

V. Claims 33-35 are drawn to a kit comprising a container comprising a solution

comprising about 0.01 to 0.05 mg/mL of tenecteplase in sterile water for injection or bacteriostatic water for injection and normal saline, and instructions for exposing the solution in an effective amount to a pathological collection of a fibrinrich fluid., classified in class 424, subclass 214.

The inventions are distinct, each from the other because of the following reasons:

DISTINCT PRODUCTS OR PROCESSES

Inventions I and II,III,IV,V are directed to related products and process. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the composition of group I can be used as a stock solution for in-situ thrombolytic assays and not as a method of treatment or a kit.

DISTINCT PROCESSES

Inventions II and III are distinct processes. Inventions are distinct if the processes as claimed are not connected in at least one of design, operation, or effect (e.g., can be made by, or used in a materially different process) and wherein at least one invention is PATENTABLE (novel and nonobvious) OVER THE OTHER (though they may each be unpatentable over the prior art) (MPEP § 802.01). The processes are distinct from one another because they recite different and distinct steps which lead to different and distinct products.

DISTINCT PRODUCTS OR PROCESSES

Inventions II, III and IV, V are directed to distinct products and processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the composition of the kits of groups IV and V can be used for *in-situ* assays not required by the methods of claims II or III.

REASON FOR RESTRICTION

The several inventions listed above are independent and distinct from one another as they have acquired a separate status in the art and require independent searches, particularly with regard to the literature searches. Clearly, a reference which would anticipate one of the above groups would not necessarily anticipate or even make obvious any of the others.

An undue burden would ensue from the examination of multiple methods which have distinct steps and end points.

ELECTION OF SPECIES

In addition if Group I is elected, a further election of species must be made. This application contains claims containing the following patentably distinct species which are described below:

The applicant must elect the liquid media for the tenecteplase from claim 1 is selected from the group consisting of: sterile water for injection or bacteriostatic water for injection and normal saline.

If Group II is elected, a further election of species must be made. This application contains claims containing the following patentably distinct species which are described below:

The applicant must elect ONE species for method of exposure from claim 10 is selected from the group consisting of: *in vivo* and *ex vivo*.

The applicant must elect ONE species for pathological collection treated from claim 17 is selected from the group consisting of: sepsis and acute respiratory distress.

If Group III is elected, a further election of species must be made. This application contains claims containing the following patentably distinct species which are described below:

The applicant must elect ONE species for co-agent from claims 23-25 selected from the group consisting of: blood thinner, anti-platelet drug, anti-coagulant drug, heparin, warfarin, aspirin, tissue-plasminogen activator, urokinase, reteplase, or a glycoprotein (GP) IIb/IIIa platelet receptor antagonist, abciximab, eptifibatide, tirofiban hydrochloride, heparin, and warfarin.

If Group IV is elected, a further election of species must be made. This application contains claims containing the following patentably distinct species which are described below:

The applicant must elect ONE species for the pathological collection from claim 30 is selected from the group consisting of: peripheral thrombosis, sepsis, and adult respiratory distress syndrome.

The applicant must elect ONE species for co-agent from claim 32 is selected from the group consisting of: abciximab, eptifibatide, tirofiban hydrochloride, heparin, and warfarin.

If Group V is elected, a further election of species must be made. This application contains claims containing the following patentably distinct species which are described below:

The applicant must elect ONE species for co-agent from claim 35 is selected from the group consisting of: abciximab, eptifibatide, tirofiban hydrochloride, heparin, and warfarin.

The species are independent or distinct because they do not belong to any art recognized group nor do they share a substantial structural feature. Art on one species does not render the others obvious.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 8, 20, 27 and 33 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and ***a listing of all claims readable thereon***, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations

of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

MULTIPLE INVENTORS

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

OCHIAI

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection

are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

CONCLUSION

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be

traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached during regular business hours, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 1651

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